

PERFORMANCE TESTED METHODSSM APPLICATION INSTRUCTIONS

Please read the entire application instructions and the Performance Tested MethodsSM Program POLICIES & PROCEDURES document before completing the application form.

- 1) Refer to the “Application Check List” (appendix 7), as a reminder of the material and information that must be submitted.
- 2) Complete the application form(s) to include the requested information on the Method Developer and method being submitted. **Complete a separate application form for each method being submitted.**
- 3) Provide the requested information concerning compliance with any regulatory requirements on the first page of the application. If the primary use of the method is to determine compliance with regulatory requirements, those regulatory agencies may be required to participate in the performance testing and review process.
- 4) The Method Developer is required to submit manufacturer-generated data for the parameters listed on the “Data Submission Requirements”, (navigation bar) where applicable.
- 5) The Method Developer is required to submit copies of method labels, manuals and informational inserts containing the information listed in the “Descriptive Product Insert Requirements” sheet. (appendix 12)
- 6) The manufacturer is required to submit the manufacturing quality assurance and quality control practices as outlined in the Performance Tested MethodsSM program Policies & Procedures document.
- 7) The Method Developer is required to include the appropriate application fee as stated on the Fee Schedule, (appendix 1). However, Do Not include a laboratory fee at the time of submission. The Laboratory fee will be invoiced after all parties have agreed on the study protocol.
- 8) Please review the Certification Mark License Agreement, (appendix 14). This agreement doesn’t need to be signed until the Performance Tested MethodSM certification has been granted, once completing a successful validation.
- 9) Submit the PTM application package to:
Managing Director
AOAC Research Institute
481 N. Frederick Ave, Ste. 500
Gaithersburg, Md. 20877-2504 USA

- 10) The Method Developer is required to submit at least three (3) method kits after the data submission is accepted and the expert reviewers have been assigned. The AOAC Research Institute will provide further instructions and addresses when appropriate. Additional method kits will be requested after the evaluation protocol has been designed, and an independent laboratory has been selected.